Claims

1. A method of monitoring the progression of diabetes from a first timepoint to a later timepoint, said method comprising the steps

providing a first biological sample obtained at the first timepoint,

measuring the concentration of glycated insulin in said biological sample,

providing a second biological sample obtained at the later timepoint,

measuring the concentration of glycated insulin in said second biological sample,

determining the difference in concentration of glycated insulin between the first and second biological samples,

wherein a lower concentration at the second timepoint is indicative of increased disease severity and/or loss of control of blood glucose.

2. A method of early diagnosis of diabetes in an individual, the method comprising the steps

providing a biological sample in which glucose levels are within a normal range from said individual,

measuring the concentration of glycated insulin in the biological sample,

wherein the presence of glycated insulin at a concentration greater than a predetermined minimum is indicative of the presence of diabetes.

3. A method of predicting the onset of diabetes in an individual, the method including the steps of;
providing a biological sample from said individual,
measuring the concentration of glycated insulin in the biological sample,
wherein the presence of glycated insulin at a concentration greater than a predetermined minimum is indicative of predisposition to diabetes.

4. The method according to claim 3, wherein the concentration of glucose in the biological sample is within the normal range.

5. The method according to claim 2 or claim 4 wherein the normal range of glucose is less than 11.1 mmol/l in a random plasma sample.

6. The method according to any one of claims 2 to 5 wherein said predetermined minimum concentration is the concentration of glycated insulin measured in a sample from the same individual at an earlier timepoint.

7. The method according to any one of claims 2 to 6, wherein said predetermined minimum concentration of glycated insulin in a non fasted sample is at least 20 pmol/l.

8. A method as claimed in any preceding claim wherein glycated insulin in the sample is measured by means of radioimmunoassay (RIA).

9. Use of glycated insulin, as a predictive marker for glucose intolerance and/or diabetes.

10. Use of glycated insulin as a predictive marker for prediabetes or to predict the onset of diabetes.

11. An *in vitro* assay method for detecting the presence of glycated insulin in a biological sample, in which glucose levels are normal, said assay method comprising the steps:
providing a biological sample;
measuring the concentration of glycated insulin in the biological sample;
wherein the presence of glycated insulin at a concentration greater than a predetermined minimum is indicative of diabetes or predisposition to diabetes.

12. The method according to claim 11, wherein the predetermined minimum is the concentration of glycated insulin measured in a sample from the same individual at an earlier timepoint.

13. The method according to claim 11 or claim 12 wherein the predetermined minimum concentration in a non fasted sample is at least 20 pmol/l.

14. An assay kit for carrying out a method according to any one of claims 1 to 8 or 11 to 13; said kit comprising at least one antibody with binding specificity to glycated insulin, means to detect binding of the at least one antibody to Glycated insulin, details of a concentration range of Glycated insulin considered to be elevated from normal levels, and instructions on how the assay is to be performed and how the results are to be interpreted..